

REMARKS

I. Introduction

The undersigned thanks Examiner Roy for the review and consideration of the present Application. In response to the non-final Office Action mailed August 4, 2009, the undersigned submits the present amendment and remarks ("Response"). Upon entry of the Response, claims 36-69 will be pending in the application. The Examiner previously withdrew claims 1-12 and 19-25 from consideration. The Response cancels claims 1-35 and adds new claims 36-69. Support for new claims may be found, among other places, in the non-limiting embodiments described and shown in pages 14-23. No new matter has been added by the Response.

The Response is believed to overcome all of the prior Office Action rejections, and allowance of the pending claims is respectfully requested.

II. Rejections based on 35 U.S.C. § 103

The Office Action rejected claims 13-18 and 26-35 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,491,702 to Heilbrun ("Heilbrun") in view of U.S. Patent No. 6,226,548 to Foley ("Foley"). Applicants respectfully traverse these rejections and request reconsideration in light of the foregoing new claims and the following remarks, withdrawal of the rejections, and allowance of all pending claims.

A. Independent Claims 36, 47, 53, and 62

Independent claims 36, 47, 53, and 62 all recite a method for performing a surgical procedure, which includes *inter alia* the following steps:

- providing a platform that includes:

- a concave surface and a convex surface, wherein the concave surface is configured to be biased against a portion of the patient's anatomy such that at least three points of the concave surface contact the portion of the patient's anatomy;
- at least one portal structure extending from the convex surface of the platform, the portal structure including a guiding structure, the guiding structure configured to guide and orient a surgical item¹ in a desired angular relationship with the portion of the patient's anatomy;
- guiding the surgical item² using the guiding structure; and
- completing the surgical procedure.

Moreover, independent claims 36 and 62 also recite *inter alia* the following steps:

- providing a platform that includes:
 - at least two fasteners configured to secure the platform to the portion of the patient's anatomy, wherein each of the fasteners is configured to be connected to bone of the individual such that at least one of the fasteners is not parallel to at least one other of the fasteners; and
 - a plurality of receptacles that extend between the concave and convex surfaces of the platform, the receptacles configured to receive the fasteners in a plurality of angulations whereby the fasteners are configured to be oriented

¹ Claim 47 requires a "portion of a drill," rather than a "surgical item."

² *Id.*

and positioned to fasten the platform to the portion of the patient's anatomy;
and

- securing the platform to the portion of the patient's anatomy using the fasteners.

B. Heilbrun

The Office Action relies primarily on Heilbrun as disclosing the recited method. Heilbrun is directed to a system for defining the location of a medical instrument relative to a patient's body via a fiducial structure that is positioned in the work space, as shown in the portion of Heilbrun Figure 2 reproduced below. Heilbrun Figure 4B (shown below) illustrates another view of the fiducial structure located in proximity to a patient's head.

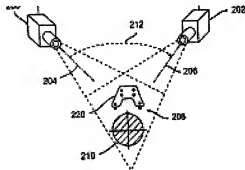


FIG. 2

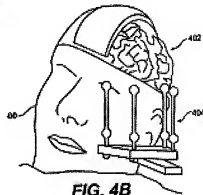


FIG. 4B

C. Foley

Foley teaches a registration device that is rigidly fixed to a spinal element. Foley Figure 2D (shown below) illustrates the use of parallel bone clamps (32) that connect the device to the patient's spinal element. Foley Figure 1A (also shown below) shows the device affixed to the spinal element.

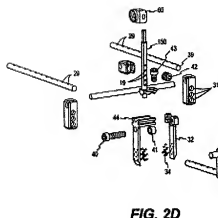


FIG. 2D

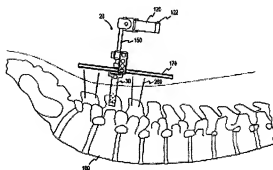


FIG. 1A

D. The References Cannot Properly Be Combined Under *KSR*.

The Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103, MPEP 2141, as revised after the Supreme Court Decision in *KSR International Co. v. Teleflex*, explain what is required where an obviousness rejection is made:

As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

(A) [Determining the scope and content of the prior art]; and
(B) Ascertaining the differences between the claimed invention and the prior art; and

(C) Resolving the level of ordinary skill in the pertinent art.

Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. . . .

Office personnel fulfill the critical role of fact-finder when resolving the *Graham* inquiries. . . . Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. . . .

Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C. 103.

MPEP §2141 (II).

Applicants submit that the Office Action failed to establish a *prima facie* obviousness case because (1) Heilbrun teaches away from the claimed invention, (2) the combination

renders Heilbrun unsatisfactory for its intended purpose, and (3) a combination of the references does not replicate the claimed invention due to claim features not found in any of the references.

First, Heilbrun affirmatively teaches away from making a connection between the platform and an individual's anatomy. The Office Action states that Heilbrun teaches "attaching the plate or platform to the patient's skin." Office Action, page 3. In contrast, Heilbrun actually states the opposite – "[n]otably, fiducial structure 220 is neither affixed to, nor in contact with, the patient's head 210." Heilbrun, col. 5, ll. 64-65. Thus, one of ordinary skill in the art would understand that Heilbrun requires that the fiducial structure not be affixed to the patient.

Second, affixing the Heilbrun fiducial structure to the patient via the fasteners of Foley renders Heilbrun's structure unsatisfactory for its intended use. "If [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)." MPEP 2143.01 V. The Heilbrun structure is intended to be "removed from workspace 208 when it is not required." Heilbrun, col. 5, ll. 66-67. "The fiducial structure 220 may be removed from the medical workspace 208 at any time after the calibration image pair has been made" Heilbrun, col. 11, ll. 8-10. Affixing the fiducial structure to the patient would prevent its subsequent removal during the procedure, thus rendering the structure unsatisfactory for its intended use. As a result, the combination is not *prima facie* obvious, and it is only

through the improper application of hind-sight reasoning that such an application would be used.

Third, even assuming *arguendo* that these references are properly combinable such that it would have been obvious to modify Heilbrun to include the fasteners of Foley, nothing in Heilbrun or Foley teach or suggest:

- providing a platform that includes:
 - a concave surface and a convex surface, wherein the concave surface is configured to be biased against a portion of the patient's anatomy such that at least three points of the concave surface contact the portion of the patient's anatomy;
 - at least two fasteners configured to secure the platform to the portion of the patient's anatomy, wherein each of the fasteners is configured to be connected to bone of the individual such that at least one of the fasteners is not parallel to at least one other of the fasteners;
 - at least one portal structure extending from the convex surface of the platform, the portal structure including a guiding structure, the guiding structure configured to guide and orient a surgical item in a desired angular relationship with the portion of the patient's anatomy;
- securing the platform to the portion of the patient's anatomy using the fasteners;
or
- guiding the surgical item using the guiding structure.

The Office Action acknowledges that Heilbrun does not teach providing fasteners recited in claims 36 and 62. Office Action, page 3. Heilbrun teaches providing a platform, but this platform does not have a concave surface, nor does it include at least one portal structure extending from a convex surface of the platform, as recited in claims 36, 47, 53, and 62. Furthermore, it would not be obvious to modify Heilbrun's platform to include these features. As discussed *supra*, Heilbrun teaches that its platform should not be affixed to the patient, therefore, it would not have been obvious perform this step or to provide the recited fasteners to do so. Because Heilbrun's platform is not intended to contact a patient's anatomy in any way, there is no reason to modify its shape to include a concave surface with at least three points of contact with the patient's anatomy. Moreover, Heilbrun's device would not properly function if its fiducial receivers were modified to include at least one portal structure extending from a convex surface of the platform because the fiducials would not be securely affixed to the platform. Thus, it would not have been obvious to modify Heilbrun's platform as recited in claims 36, 47, 53, and 62.

Foley does not supply the missing elements. Foley clearly does not teach the recited steps for the platform and portal structure. Foley also do not teach or suggest the recited steps for the fasteners in claims 36 and 62. Foley's clamp (30) has two blades (32) that extend parallel to one another to grip the spinal element. The blades are pulled toward one another via screw (40). Foley, col. 6, ll. 54-57. Thus, Foley does not teach or suggest each and every element of claims 36, 47, 53, and 62.

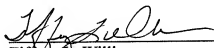
Because neither Heilbrun nor Foley appear to teach or suggest the missing elements, in combination they fail to render obvious the subject matter of independent claims 36, 47,

53, and 62. These claims are therefore allowable. Dependent claims 37-46, 48-52, 54-61, and 63-69 are allowable at least by virtue of their ultimate dependence from one of allowable independent claims 36, 47, 53, and 62. Applicants respectfully request reconsideration and withdrawal of these rejections.

CONCLUSION

The new claims and the above remarks completely respond to the Office Action and place the application in condition for allowance, which is respectfully requested. **EXCEPT** for the issue fees payable under 37 C.F.R. § 1.18, the Director is authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 C.F.R. §§ 1.16 and 1.17 that may be required, including any required extension of time fees, or credit any overpayment to Deposit Account Number 11-0855. This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3). If there are any matters that can be addressed by telephone, the Examiner is respectfully urged to contact the undersigned attorney at 404-815-6608.

Respectfully submitted,



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